_____ BILL NO. _____

INTRODUCED BY _____
(Primary Sponsor)

A BILL FOR AN ACT ENTITLED: “AN ACT CREATING AN INSULIN SAFETY NET PROGRAM; ESTABLISHING REQUIREMENTS FOR PROGRAM PARTICIPATION; REQUIRING LICENSING OF MANUFACTURERS OF INSULIN SOLD IN MONTANA; REQUIRING MANUFACTURERS TO REIMBURSE OR REPLACE INSULIN DISPENSED UNDER THE PROGRAM; ESTABLISHING REPORTING REQUIREMENTS; PROVIDING RULEMAKING AUTHORITY; PROVIDING DEFINITIONS; AND PROVIDING AN EFFECTIVE DATE AND A TERMINATION DATE.”

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. **Section 1. Short title.** [Sections 1 through 10] may be cited as "The Montana Insulin Safety Net Program Act".

NEW SECTION. **Section 2. Definitions.** For the purposes of [sections 1 through 10], the following definitions apply:

(1) "Board" means the board of pharmacy provided for in 2-15-1733.

(2) "Eligible individual" means a person meeting the requirements of [section 4].

(3) "Manufacturer" means a manufacturer, as defined in 37-7-602, of insulin products sold in this state.

(4) "Pharmacy" means an established location that is licensed by the board pursuant to Title 37, chapter 7, where drugs are dispensed with pharmaceutical care.

(5) "Urgent need of insulin" means having readily available for use less than a 7-day supply of insulin and needing insulin in order to avoid the likelihood of suffering significant health consequences.

NEW SECTION. **Section 3. Insulin safety net program -- board responsibilities.** (1) There is an insulin safety net program to ensure access to insulin for individuals in urgent need of insulin.

(2) The board shall develop an application form for use by an eligible individual and make the form available on the board's website to:

(a) pharmacies;

(b) health care providers who prescribe or dispense insulin; and

(c) hospitals and clinics.

(3) The application form must:

(a) allow the individual to attest to the eligibility requirements of [section 4]; and

(b) notify the applicant that the form will be retained and may be reviewed to verify the applicant's eligibility, including whether the applicant has obtained insulin under the safety net program in the previous 12 months.

(4) (a) The board shall notify the following entities by mail or e-mail of the availability of the program:

(i) Montana pharmacies;

(ii) the department of public health and human services provided for in 2-15-2201; and

(iii) a statewide association representing pharmacies and pharmacists;

(b) The notification must include a description of the program, the application process for eligible individuals, the manner in which pharmacies may file claims for reimbursement or replacement of insulin provided under the program, and the process for filing a complaint with the board if a manufacturer fails to replace the insulin or reimburse the pharmacy.

NEW SECTION. **Section 4. Program eligibility -- penalties.** (1) An individual is eligible for the insulin safety net program if the individual:

(a) is a Montana resident;

(b) has a valid insulin prescription;

(c) is not enrolled in the healthy Montana kids plan provided for in Title 53, chapter 4, part 11, or the medical assistance program provided for in Title 53, chapter 6;

(d) does not have a prescription drug coverage plan that limits the cost-sharing amount for the individual to $75 or less, including copayments, deductibles, or coinsurance, for a 30-day supply for at least one insulin in each category of insulin, regardless of the amount of insulin needed;

(e) has not received insulin through the insulin safety net program in the previous 12 months; and

(f) is in urgent need of insulin.

(2) By submitting a completed, signed, and dated application to a pharmacy, the individual attests that the information in the application is correct. An individual who falsifies information in an application for the insulin safety net program shall reimburse the manufacturer for the cost of the insulin received.

NEW SECTION. **Section 5. Insulin safety net program -- pharmacy responsibilities.** (1) (a) A pharmacy may dispense a 30-day supply of insulin prescribed to an eligible individual if the individual provides the pharmacy with:

(i) a completed, signed, and dated application form;

(ii) a valid insulin prescription; and

(iii) a current Montana identification card, driver's license, driver's permit, school district or postsecondary education photo identification, tribal photo identification, or other valid government-issued photo identification, including but not limited to a passport or military or state-issued identification.

(b) If the eligible individual is under 18 years of age, the individual's parent or legal guardian shall provide the pharmacy with the required proof of residency.

(2) The pharmacy may collect an insulin copayment from the individual to cover the pharmacy's cost of processing and dispensing the insulin. The copayment may not exceed $35.

(3) The pharmacy may notify the health care provider who issued the prescription that the individual has received insulin through the insulin safety net program.

(4) The pharmacy may submit to the manufacturer of the dispensed insulin product or to the manufacturer's vendor a claim for payment that covers the pharmacy's wholesale acquisition cost unless the manufacturer agrees to send the pharmacy the same insulin that was dispensed, in the amount dispensed. In submitting the claim, the pharmacy may not provide personally identifiable information about an eligible individual unless the manufacturer has entered into a business associate contract with the pharmacy.

(5) The pharmacy may provide an eligible individual with information on:

(a) manufacturer or foundation-based patient assistance programs;

(b) medical assistance programs administered by the state; and

(c) providers who participate in prescription drug discount programs.

(6) A pharmacy may confirm to another pharmacy whether it has dispensed insulin under this part within the previous 12 months to a person requesting insulin from the inquiring pharmacy through the insulin safety net program.

(7) The pharmacy shall provide the board with:

(a) the number of individuals who received insulin through the safety net program;

(b) the amount of insulin dispensed under the program;

(c) the amount of insulin that was replaced or reimbursed; and

(d) the number of instances in which the pharmacy did not receive replacement insulin or reimbursement of insulin dispensed under the program and the amount and cost of the insulin involved.

(8) A pharmacy participating in the insulin safety net program is not required to fill a request from an eligible individual if the pharmacy is out of stock of the brand of insulin requested by the eligible individual but may offer to order the insulin and provide it to the eligible individual when the insulin is in stock.

NEW SECTION. **Section 6. Insulin safety net program -- manufacturer registration and responsibilities -- penalties.** (1) By July 1, 2022, a manufacturer of insulin sold in this state shall:

(a) obtain a license from the board;

(b) pay an annual license set by the board by rule commensurate with costs; and

(c) comply with the provisions of [sections 1 through 10].

(2) A manufacturer shall reimburse a pharmacy for insulin provided to an eligible individual or replace the insulin that was provided to the eligible individual within 7 days of receiving the pharmacy's claim for reimbursement or replacement.

(3) Failure to comply with the requirements of [sections 1 through 10] constitutes unprofessional conduct.

(4) The board shall investigate complaints against and impose penalties as provided in 37-1-312 for each violation of [sections 1 through 10].

NEW SECTION. **Section 7. Confidentiality of data.** (1) Data collected on eligible individuals

assisted by the insulin safety net program is confidential and may be used only for:

(a) safety purposes;

(b) a pharmacy to verify to another pharmacy whether an applicant has received insulin under the safety net program in the previous 12 months, if a pharmacy chooses to ask for the information;

(c) a manufacturer to carry out administrative and fraud-detection activities; or

(d) investigating alleged violations of [sections 1 through 10].

NEW SECTION. **Section 8. State and federal antikickback provisions.** An individual, pharmacy, manufacturer, third-party administrator, or other person may not, as part of the person's participation in or administration of the insulin safety net program, request, seek, or cause another individual, pharmacy, manufacturer, third-party administrator, or other person to request or seek any reimbursement or other payment for insulin provided pursuant to [sections 1 through 10] from a plan or program that provides health benefits and is funded directly, in whole or in part, by the United States government or the state.

NEW SECTION. **Section 9. Rulemaking.** The board may adopt rules to implement the provisions of [sections 1 through 10], including but not limited to rules related to:

(1) the license fee for manufacturers;

(2) the process a pharmacy must follow to submit a claim for reimbursement or replacement of insulin; and

(3) reporting requirements for pharmacies and manufacturers.

NEW SECTION. **Section 10. Reports and program review.** (1) By February 15 each year, each manufacturer subject to [sections 1 through 10] shall report to the board the following information for the previous calendar year:

(a) the number of eligible individuals who accessed and received insulin through the insulin safety net program; and

(b) the wholesale acquisition cost of the insulin provided by manufacturers.

(2) (a) The board shall review data submitted by pharmacies pursuant to [section 5] and report to the

legislature, in accordance with 5-11-210, on the use of the insulin safety net program, including but not limited to:

(i) the number of applications filed;

(ii) the amount of insulin dispensed;

(iii) the number of pharmacies participating in the program and the number receiving replacement insulin or reimbursement;

(iv) the number of manufacturers that failed to comply with program requirements; and

(v) the information reported by manufacturers under this section.

(b) The board shall provide copies of the report to the children, families, health, and human services interim committee and to the economic affairs interim committee.

NEW SECTION. **Section 11. Codification instruction.** [Sections 1 through 10] are intended to be codified as an integral part of Title 37, chapter 7, and the provisions of Title 37, chapter 7, apply to [sections 1 through 10].

NEW SECTION. **Section 12. Effective date.** [This act] is effective July 1, 2021.

NEW SECTION. **Section 13. Termination.** [This act] terminates June 30, 2024.

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